DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 31, 2016

Rex Medical
c/o Ms. Susan Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K113103
Trade/Device Name: SplitWire Percutaneous Transluminal Angioplasty Scoring Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: PNO
Dated: April 16, 2012
Received: April 20, 2012

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of May 22, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K113103

Device Name: SplitWire Percutaneous Transluminal Angioplasty Scoring Device

Indications for Use:

The SplitWire Percutaneous Transluminal Angioplasty Scoring device is indicated for the use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use __X____ **(Per 21 CFR 801.109)** OR **Over-The Counter Use**_____ **(Optional Format 1-2-96)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113103

MAY 2 2 2012

1100 East Hector Street, Suite 245, Conshohocken, PA 19428

510(K) SUMMARY

This summary of 510(k) information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K113103

1. Submitter's Identification:

Rex Medical, LP
1100 East Hector Street
Suite 245
Conshohocken, PA 19428
610-940-0665

Contact: Mr. Walter H. Peters
Quality Manager

Date Summary Prepared: October 14, 2011

2. Name of the Device:

SplitWire Percutaneous Transluminal Angioplasty Scoring Device

3. Predicate Device Information:

VascuTrak PTA Dilation Catheter (K063657)

4. Device Description:

The SplitWire Percutaneous Transluminal Angioplasty Scoring Device is designed to facilitate the dilatation of stenoses.

The SplitWire device is intended to be used with a percutaneous transluminal angioplasty balloon catheter.

The SplitWire device consists of two (2) wires that are joined at the distal end. The larger wire (scoring wire) has a triangular profile near the distal end, that when the balloon is inflated applies pressure to the lesion being treated. The smaller wire (tracking wire) is used to position the PTA balloon catheter in the

proper location adjacent to the lesion. There are two (2) radiopaque markers bands on the tracking wire that indicate the location for the PTA balloon catheter placement.

The distal section of the SplitWire is designed to be atraumatic with a radiopaque coil for visibility. The distal section is coated with a soft polymer.

The device is used in the same manner as the predicate device and other substantially equivalent 510(k) cleared devices.

5. **Intended Use:**

The SplitWire Percutaneous Transluminal Angioplasty Scoring device is indicated for the use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

6. **Comparison to Predicate Devices:**

Attribute	SplitWire PTA Scoring Device	VascuTrak PTA Dilation Catheter (K063657)
Indication For Use	intended for the use with percutaneous transluminal angioplasty (PTA) catheters to facilitate dilation of stenoses in the iliac, femoral, ilio-femoral, popliteal , infra-popliteal, and renal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	intended to dilate stenosis in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal arteries and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Overall Device Length	90cm, 180cm, 260cm	80cm, 140cm
Balloon Length	Compatible with balloon lengths of 20-80mm	20mm, 40, 60, 80, 100, 120, 150, 200, 250, 300
Balloon Diameter	Unlimited	2-7mm
Integrated Balloon	No	Yes
Scoring Members	1	1 plus procedural guidewire
Scoring Member Profile	Triangular	Round
Scoring Member Size	.014"	.010", .018" procedural guidewire
Scoring Member fixed to balloon	No	No
Rated Burst Pressure	Dependent on RBP of balloon used	12atm
Guidewire Compatibility	.035" or .018"	.018"

Introducer Compatibility	Dependent on the introducer compatibility of the balloon used	7Fr
Single Use	Yes	Yes
Sterilization	Ethylene Oxide Process	Ethylene Oxide Process

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence:

Comparative functional testing to the predicated devices was performed based on device attributes, performance and safety. Bench testing was conducted to ensure that the SplitWire device performed as intended. Testing included:

- General requirements for intravascular catheters: ISO 10555-1
- Angioplasty Catheter Dilation Performance Testing
- Compatibility with PTA Balloon Catheters
- Simulated Use Testing

In Vivo GLP animal testing (Reference Exhibit 8) showed equivalence during use for safety. Testing results revealed the subject device to be substantially equivalent to the predicate device.

8. Conclusions:

The subject device, the SplitWire Percutaneous Transluminal Angioplasty Scoring Device, has the same intended use as the predicate device, the VascuTrak PTA Dilation Catheter (K063657). Bench testing and non-clinical testing supplied within our submission demonstrates that there are not any differences in their technological characteristics thereby not raising any new questions of safety and effectiveness. Therefore, the SplitWire Percutaneous Transluminal Angioplasty Scoring Device is substantially equivalent to the predicate device, the VascuTrak PTA Dilation Catheter (K063657).